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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/626,166	07/23/2003	Gregory Everett Amidon	PC28053	9717
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EXAMINER				
ROGERS, JAMES WILLIAM				
ART UNIT		PAPER NUMBER		
1618				
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01/29/2009		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/626,166

**Applicant(s)**

AMIDON ET AL.

**Examiner**

JAMES W. ROGERS

**Art Unit**

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 December 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SG/US)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Response to Arguments***

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the reasons set forth in the previous office action filed 06/06/2008.

Applicant's arguments filed 12/08/2008 have been fully considered but they are not persuasive.

Applicants assert that the phrase within the claims "at a solid fraction representative of the tablet" addresses the issues raised in the previous action and the specification discloses that the tensile strength is determined by the starch compact, which is a compressed tablet that consists only of starch.

The examiner agrees that tensile strength as determined by a starch compact would not be indefinite at least in regards to whether the tensile strength is referring to the entire tablet, the combination of hydrophilic polymer and starch or just starch alone. However applicants have not defined the tensile strength of the starch in their claims by stating that the tensile strength is referring to a starch compact containing just the claimed starch. Therefore the claim is still indefinite with respect to whether the tensile strength is referring to the entire tablet, the combination of hydrophilic polymer and

starch or just starch alone. If applicants wish to remove this rejection the solution is simple, delete the recitation "at a solid fraction of the tablet" and include a recitation that clarifies the tensile strength of the starch is determined by a starch compact containing only the claimed starch.

Applicants assert that since any suitable test can be used to measure the tensile strength the rejection should be removed since three different tests were conducted within the specification and all the tests results for tensile strength were essentially the same.

While applicants may have a valid point that the test used to measure the tensile strength is not necessary to recite in their claims since the specification shows that any suitable test can be used to measure the tensile strength. However as noted in the previous office action tensile strength is an intensive property which means that its value not only depends upon the material itself but also the preparation of the sample (compression forces used to mold tablet for example) and the temperature in which the test was conducted. Applicants have not provided sufficient information within the claimed subject matter for one of ordinary skill in the art to measure the claimed tensile strength since it is an intensive property dependent upon the manufacture of the tablet used to measure the tensile strength.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4,8-9,13-20 and 24-26 are rejected under 35 U.S.C. 102(e) as being anticipated by Holman (US 6,277,875 B1, cited by applicants), for the reasons set forth in the previous office action filed 06/06/2008.

Claims 1-4,8-4,19-20,22,24 and 26 are rejected under 35 U.S.C. 102(e) as being anticipated by Patel et al. (US 2003/0180352), for the reasons set forth in the previous office action filed 06/06/2008.

Applicant's arguments filed 12/08/2008 have been fully considered but they are not persuasive.

Applicants assert that since neither reference above discloses starch with the claimed tensile strength, which they purport is not indefinite, the examiner must consider the limitation and not ignore it.

As already mentioned by the examiner in previous actions there is no patentable distinction within applicant's claims that would preclude the formulations of Holman and Patel, since the two compositions are essentially the same it is inherent that the ingredients will have the same tensile strength. Also as previously stated by the examiner commercially available starches as described within the Michaud reference have a tensile strength greater than applicants claimed lower limit. Lastly since applicants have not disclosed at least within their claims what features are present within their claimed starch that would lead to the claimed tensile strength, such as the

ratio of amylase/amylopectin or the molecular weights of the two carbohydrate glucoses the only feature that must be present in applicant's claims is pre-gelatinized starch. Since both Homan and Patel teach compositions containing pre-gelatinized starch the limitation is considered met because it is inherent that the same composition/compound will have the same properties. Furthermore it appears as though applicants may be attempting to claim a property of an old and known composition. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case or either anticipation or obviousness has been established, Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-22 and 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holman (US 6,277,875 B1) alone or alternatively in view of Michaud et al. (EP 0,933,079 A1, cited previously), for the reasons set forth in the previous office action filed 06/06/2008.

Claims 1-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Patel et al. (US 2003/0180352) alone or alternatively in view of in view of Michaud et al.

(EP 0,933,079 A1, cited previously), for the reasons set forth in the previous office action filed 06/06/2008.

Claims 1-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holman (US 6,277,875 B1, cited by applicants) in view of Khan et al. (US 5,656,296, cited by applicant) in view of Petrus et al. (WO 00/59477 A1, cited by applicants) in further view of Michaud et al. (EP 0,933,079 A1, cited by applicants), for the reasons set forth in the previous office action filed 06/06/2008.

Applicant's arguments filed 12/08/2008 have been fully considered but they are not persuasive.

Applicants assert that Michaud is drawn to immediate release formulations thus there would be no reasonable expectation of success nor motivation to arrive at applicant's claimed sustained release formulation. Applicants also assert that since Michaud discloses that the starch dissolves at a very high speed, the reference teaches away from applicants claimed sustained release formulation.

The examiner respectfully disagrees with the above assertions by applicants. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Michaud was only used for its description of the tensile strength of various starches and as a secondary reference it does not have to disclose all of applicants claimed invention. The primary references disclose sustained release formulations and as noted previously,

one of ordinary skill in the art would have been motivated to combine the Michaud with Homan and Patel in order to achieve the disclosed advantages of the starches described in Michaud which produced hard tablets at low compression rates, a feature that would obviously be advantageous in industrial production and processability of a tablet.

### ***Conclusion***

No claims are allowed at this time.

Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 271-0616. The fax phone number for



the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Michael G. Hartley/

Supervisory Patent Examiner, Art Unit 1618